IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Sidney Smith et al.
Appl. No.: 09/813,351
Conf. No.: 3473
Filed: March 19, 2001
Title: LARGE VOLUME FLEXIBLE CONTAINER
Art Unit: 3727
Examiner: Jes F. Pascua
Docket No.: CRTS-5679 (0112713-968)

Assistant Commissioner of Patents

Washington, D.C. 20231

AFFIDAVIT OF WILLIAM S. HURST UNDER 37 C.F.R. § 1.132

Sir:

I, William S. Hurst, hereby state as follows:

1. I am one of the named inventors of the above-identified patent application and I am therefore familiar with the inventions disclosed therein. I have recently reviewed the claims of the patent application as they are currently pending. A copy of the pending claims is attached hereto at Exhibit 1.

2. The present claims are directed to a large volume flexible container for holding at least 200 L of a bio-fluid. The large volume flexible container is designed to be placed within a rigid support container. The rigid container supports the significant loads imparted by the fluid forces within the flexible container. Unsupported areas of the flexible container are prone to rupture and are undesired. Unsupported areas of the flexible container may occur as a result of a poor fit between the flexible container and the rigid container and wrinkling of the flexible container.

3. A reference relied upon by the Patent Office is U.S. Patent No. 5,988,422 to Vallot (*Vallot*). A copy of the *Vallot* patent is attached hereto at Exhibit 2. I have reviewed the *Vallot* patent. *Vallot* discloses a parallelepiped-shaped sachet for transporting bio-

pharmaceutical fluids. *Vallot* also discloses that a parallelepiped-shaped container may be made by cutting a film at 30°-60° relative to the vertical axes of the film. *Vallot*'s 30°-60° angle range is the same as the 120°-150° angle range between the panel peripheral edge and the end segment tapered edge with respect to the present claim language angle range.

4. I directed the preparation of four models of large volume fluid-filled flexible containers placed in rigid support containers. These models were prepared using finite element analysis. The first model depicts a container having a 120° angle between the panel peripheral edge and the end segment tapered edge and represents *Vallot's* lower angle limit of 30°. Cross sectional views of the first container model are set forth at Tab A. The second model depicts a container having a 150° angle between the panel peripheral edge and the end segment tapered edge and represents *Vallot's* upper angle limit of 60°. Cross sectional views of the second container model are set forth at Tab B. The third model depicts a container having a 135.01° angle between the panel peripheral edge and the end segment tapered edge and represents the lower angle limit of 135.01° for the claimed container. Cross sectional views of the third container model are set forth at Tab C. The fourth model depicts a container having a 138° angle between the panel peripheral edge and the end segment tapered edge and represents the upper angle limit of 138° for the claimed container. Cross sectional views of the fourth container are set forth at Tab D.

5. The first model having a 120° angle (Tab A) fails to provide a usable container. An angle of 120° yields a container having an arcuate bottom portion. This arcuate bottom portion results in a large areas of the flexible container that are unsupported by the support container. These unsupported areas of the container are prone to rupture resulting in a flexible container that is not viable.

6. The second model having a 150° angle (Tab B) also fails to provide a usable container. An angle of 150° produces a container that experiences extreme wrinkling. Wrinkles are harmful as they act to fracture the film and leak when subjected to sustained dynamic loads that occur during shipping. Wrinkles are further undesired because they manifest themselves as fluid dams preventing accurate dispensing, draining, and filling of the flexible container.

7. The third model having a 135.01° angle (Tab C) provides a usable container. As shown at Tab C, this container is fully supported by the rigid support container. Full support is important as it reduces stressing of the flexible container, correspondingly reducing the possibility of leakage. The container with a 135.01° angle was found to be the lower limit with respect to a workable container. An angle less than 135.01° does not enable the end panel to move outward beyond the sleeve end plane. This ability of the end panel to move outward enables the flexible container to be fully supported by the rigid support container.

8. The fourth model having a 138° angle (Tab D) provides a usable container. The container is fully supported by the support container. The container with a 138° degree angle also experiences minimal wrinkling. An angle of 138° was found to be the upper limit with respect to a workable container. An angle greater than 138° yields excessive wrinkling and poses too great a risk of rupture for use.

9. Based on my review of *Vallot*, and our modeling and experimentation, *Vallot* does not disclose a large volume flexible container having an angle range of 135.01° to 138° between the panel peripheral edge and the end segment tapered edge. *Vallot* appears to recognize the need to fully support the sachet with a rigid support container as *Vallot* discloses that the sachet is to conform exactly to the geometry of the rigid support container. However, the broad angle range of 30°-60° (120°-150°) disclosed in *Vallot* contradicts this as sachets conforming to *Vallot's* broad angle range would be unacceptable for use. The first model (Tab A) clearly indicates that a container having *Vallot's* 30° angle (120) would not be acceptable for use. In addition, it is clear that *Vallot* fails to appreciate or recognize the problems associated with wrinkling. This is apparent as the second model (Tab B) depicting a container with a 150° angle experiences excessive wrinkling and would not be acceptable for use. *Vallot* provides no guidance how to overcome the problems of fully supporting the flexible container in combination with wrinkle avoidance.

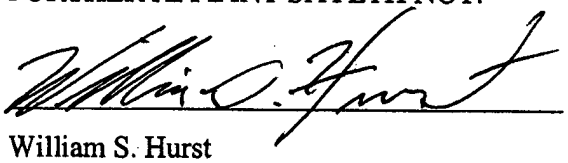
10. At most, *Vallot* discloses a flexible container having a 45° angle, that is a parallelepiped shape, with the top and bottom faces being parallel. *Vallot's* broad angle range

includes unusable containers. Thus, the only concrete example of a workable container in *Vallot* is a container having a 45° (135°) angle. *Vallot* repeatedly describes the container as having a parallelepiped shape and that the top and bottom faces of the container are parallel to each other. This indicates that *Vallot* is only concerned with a container having a 135° (45°) angle between the panel peripheral edge and the end segment tapered edge.

11. Our container having an angle range of 135.01° to 138° as recited in the claims yields unexpected results. The angle range of 135.01° to 138° provides a flexible container that is fully supported by the rigid support container. This angle range permits the end panels to extend outward thereby enabling full support of the flexible container by the support container. A parallelepiped container such as *Vallot's* container having an angle of 45° is incapable of having an end panel that extends beyond the fold line. Our angle range of 135.01°-138° also provides a flexible container with minimal wrinkling. The combination of these features advantageously yields a flexible container that is rupture resistant because it is wrinkle-free and fully supported by the support container and the container is readily drained without leaving bio-fluid within the container.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of any patent that may issue from this application.

FURTHER AFFIANT SAYETH NOT:



William S. Hurst

October 17, 2005

Date

Listing of Claims:

Claim 1 (canceled)

Claim 2 (previously presented): The container of claim 17 wherein the panels form a polygonal sleeve.

Claims 3-5 (canceled)

Claim 6 (previously presented): The container of claim 17 wherein the plurality of panels comprises four panels cooperatively forming a sleeve having a generally rectangular cross-section.

Claim 7 (original): The container of claim 6 wherein two opposing panels are gusseted panels.

Claim 8 (original): The container of claim 7 wherein the gusseted panels have a gusset fold.

Claims 9-11 (canceled)

Claim 12 (previously presented): The container of claim 17 wherein the end segments converge to a line.

Claim 13 (canceled)

Claim 14 (previously presented): The container of claim 17 wherein one of the panels has a port.

Claim 15 (previously presented): The container of claim 14 wherein the port has a port closure in sterile communication with the port, the port closure providing sterile access to the container interior.

Claim 16 (canceled)

Claim 17 (currently amended): A flexible container composed of a polymeric material for holding at least 200L of fluid comprising:

a plurality of panels, each panel having a peripheral edge, an end, and an end segment extending from the end, the end segment having a tapered peripheral edge extending from a corresponding peripheral edge and forming an angle therebetween, the plurality of panels joined together along the peripheral edges to form a sleeve, the panels each having a fold line that cooperate to define an imaginary plane at one end of the sleeve;

an end panel composed of the plurality of end segments folded at the fold line and sealed to each other along the tapered peripheral edges, at least one angle having a range from 135.01° to about 138° and forming at least one end segment with an additional amount of material which permits at least a portion of the end panel to extend outwardly from the sleeve beyond the imaginary plane when the container is filled ~~first end panel is in an unfolded position~~; and

a second end panel formed at another end of the sleeve to form a closed flexible container.

Claim 18 (currently amended): The container of claim 17 wherein the panels each have a second end and a second end segment extending from each second end, each second end segment having a tapered peripheral edge extending from a corresponding peripheral edge and forming an angle therebetween, the panels each having a second fold line that cooperate to define a second imaginary plane at the second end of the sleeve, the second end panel composed of the plurality of the second end segments, folded at the fold line and sealed to each other along the tapered peripheral edges, at least a second angle having a range from 135.01° to about 138° and forming at least one second end segment with an additional amount of material which permits at least a portion of the second end panel to extend outwardly from the sleeve beyond the second imaginary plane when the container is filled.

Claim 19 (previously presented): The container of claim 17 further comprising first and second opposing side panels wherein the first and second opposing panels are folded on top of themselves when the flexible container is in a folded position.

Claim 20-21 (canceled)

Claim 22 (previously presented): The container of claim 17 wherein the at least one angle is in the range from about 135.5° to about 136.5°.

Claim 23 (previously presented): The container of claim 17 wherein the at least one angle is 136°.

Claim 24-28 (canceled)

Claim 29 (previously presented): The flexible container of claim 17, further comprising a plurality of spaced-apart hanger connection locations at a top side of the flexible container, the hanger connection locations positioned inward from an outer edge of the top side.

Claim 30 (previously presented): The flexible container of claim 17, wherein the end panel extending outwardly beyond the imaginary plane is a bottom side of the flexible container.

Claim 31 (previously presented): The flexible container of claim 17, wherein the first end panel extending outwardly beyond the imaginary plane has a generally vertical orientation.

Claims 32-35 (canceled)

Claim 36 (previously presented): The container of claim 15 wherein the port closure further comprises a communication member having an end attached to the port.

Claim 37 (previously presented): The container of claim 36 wherein the communication member has a length of about six feet to about 30 feet.

Claim 38 (previously presented): The container of claim 36 further comprising a stop member attached to a second end of the communication member.

Claim 39 (previously presented): The container of claim 38 wherein the stop member is a gas permeable, sterile barrier.

Claim 40 (previously presented): The container of claim 39 wherein the barrier prevents fluid from passing into the communication member.

Claim 41 (previously presented): The container of claim 38 further comprising a cover member.

Claim 42 (previously presented): The container of claim 41 wherein the cover member covers the stop member and a portion of the second end of the communication member.

Claim 43 (previously presented): The container of claim 15 further comprising a second port and a vent closure in sterile communication with the second port.

Claim 44 (previously presented): The container of claim 43 wherein the vent closure further comprises a vent tube having an end attached to the second port.

Claim 45 (previously presented): The container of claim 44 wherein the vent closure further comprises a vent plug attached to a second end of the vent tube.

Claim 46 (previously presented): The container of claim 45 wherein the vent plug is a gas permeable sterile barrier to the vent tube.

Claim 47 (previously presented): The container of claim 46 wherein the vent plug equalizes the internal and external container pressure.

Claim 48 (previously presented): The container of claim 47 wherein the vent plug permits complete filling of the container.

Claim 49 (previously presented): The container of claim 48 further comprising a vent valve disposed within said vent tube.

Claim 50 (canceled)

Claim 51 (previously presented): The container of claim 17 further comprising a plurality of spaced-apart hanger connectors on a top panel of the plurality of panels, the hanger connectors being located between a center of the top panel and an outer perimeter edge of the top panel.

Claim 52 (previously presented): The container of claim 17 wherein the entire end panel extends beyond the imaginary plane.

Claim 53 (previously presented): The container of claim 18 wherein the entire second end panel extends beyond the second imaginary plane.

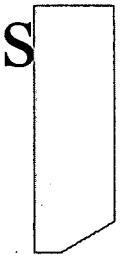
Claim 54 (previously presented): The container of claim 18 wherein each end segment has opposing tapered peripheral edges.

Claim 55 (previously presented): The container of claim 18 wherein the at least second angle is in the range from about 135.5° to about 136.5°.

Claim 56 (previously presented): The container of claim 18 wherein the at least second angle is 136°.

Container End Seal Angle Analysis

Case 1 – 120 deg



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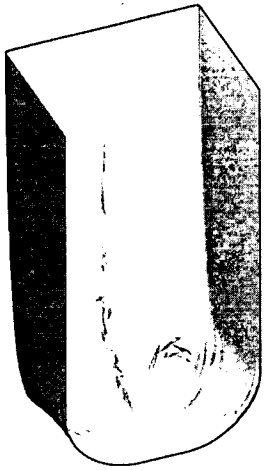
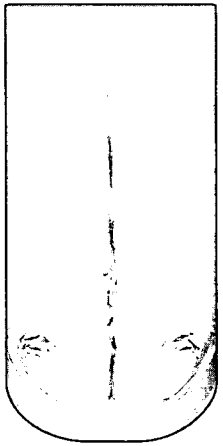
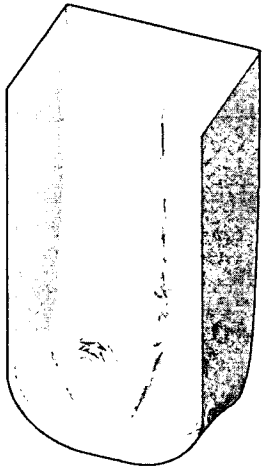
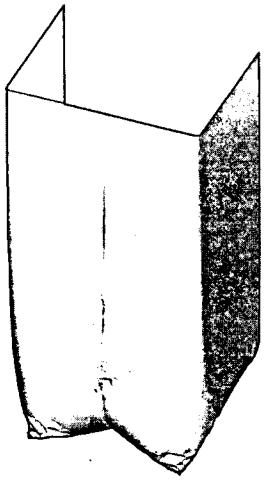
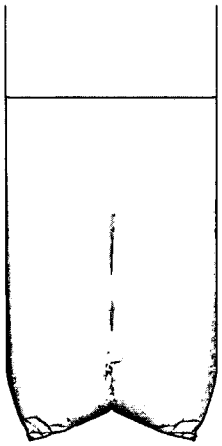
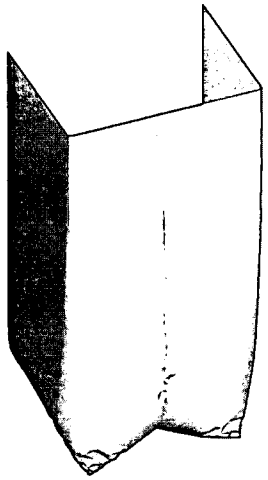








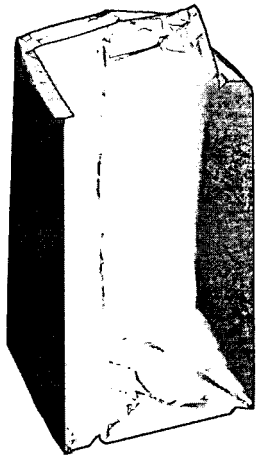


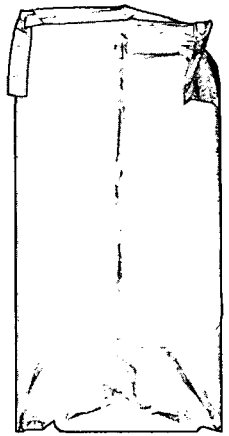


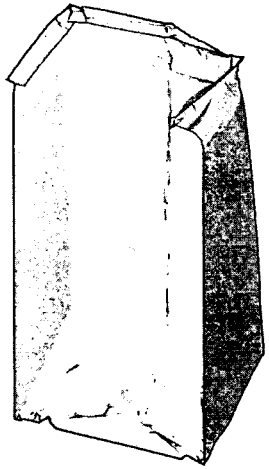
Container End Seal Angle Analysis

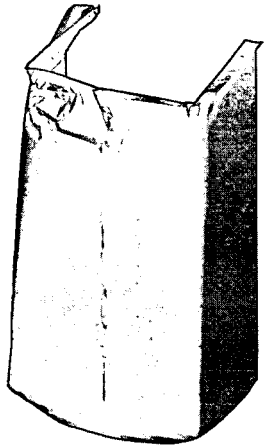
Case 1 – 150 deg

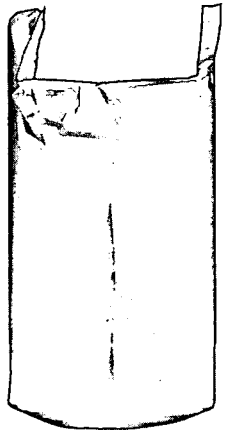
½ bag profile

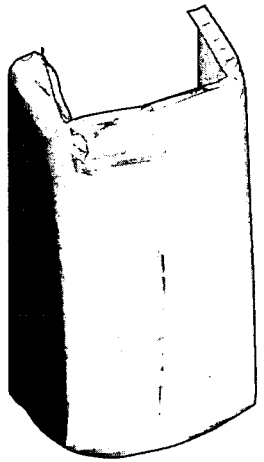






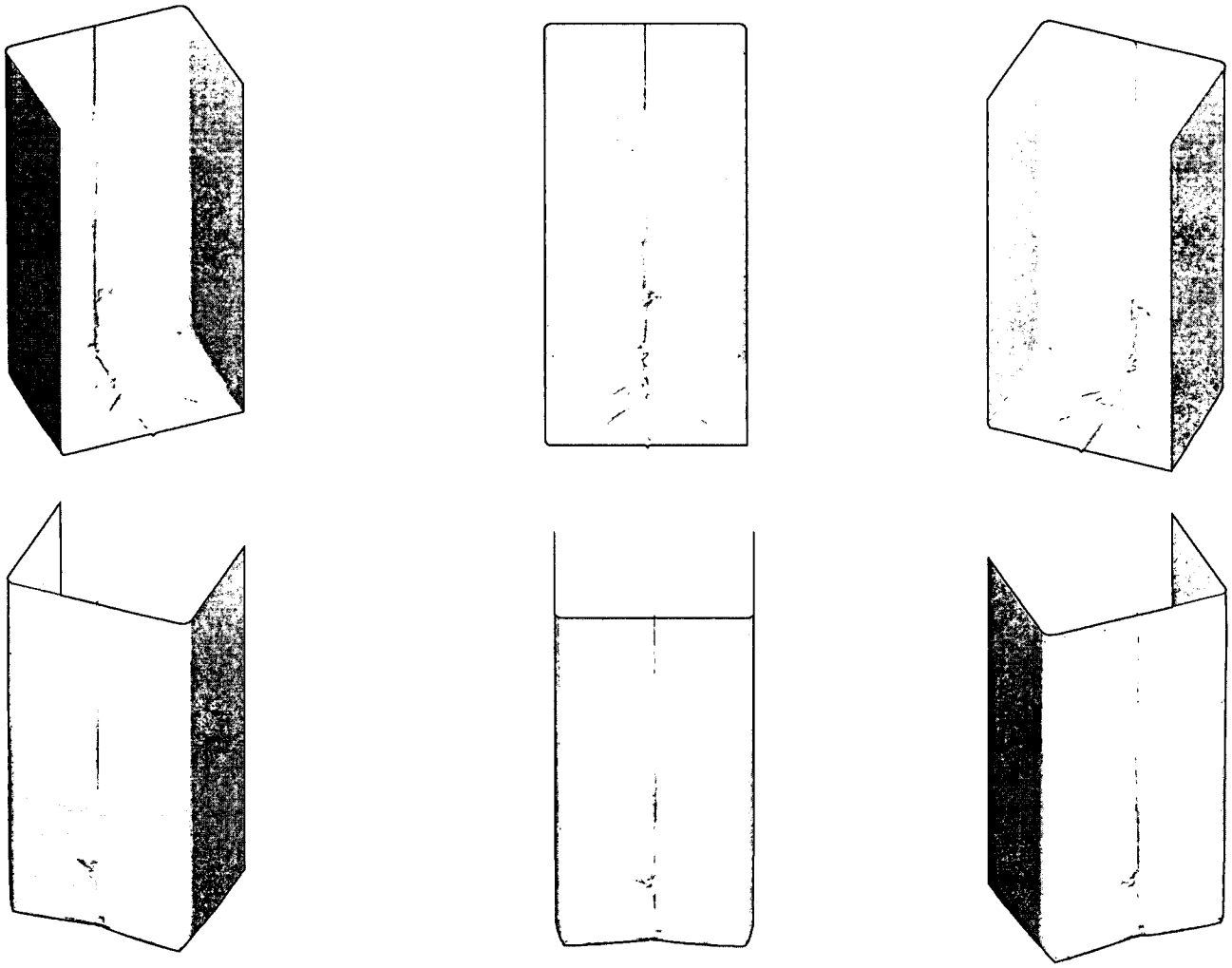






Container End Seal Angle Analysis

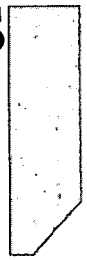
Case 1– 135.01 deg



½ bag profile

Container End Seal Angle Analysis

Case 1 – 138 deg



½ bag profile